

**Pneumococcal Disease Prevention in Adults:
Potential Vaccine Strategies**

September 9-10, 2003

Four Points Sheraton in Washington DC (K street)

Agenda

Day 1-September 9, 2003

Morning Session

9:00-9:15 a.m.

Introduction - Goals of the meeting

Bruce Gellin, M.D.

Director, National Vaccine Program, DHHS

Immunology (9:15-10:30 a.m)

9:15-9:25 a.m.

Chair: Ann Arvin, M.D.

Professor of Pediatrics and of Microbiology and
Immunology, Stanford University School of Medicine

9:25-9:45 a.m.

Basic and clinical immunology of pneumococcal vaccines

Richard A. Insel, M.D.

Executive Vice President of Research,
Juvenile Diabetes Research Foundation (JDRF)

9:45-10:05 a.m.

***Immune responses (to polysaccharides) in
immunosuppressed Individuals***

Donna Ambrosino, M.D.

Associate Professor of Pediatrics
Dana Farber Cancer Institute of Infectious Diseases

10:05-10:30 a.m

**Panel Discussion: *What does the basic immunology
teach us for design of clinical trials: Insights with respect
to correlates and/or endpoints***

Richard Insel, Donna Ambrosino, Ann Arvin

10:30-10:40 a.m.

Break

Epidemiology of pneumococcal infection (10:40- 12noon)

- 10:40-11:00a.m** ***Pneumococcal disease (invasive) in adults***
Chair: Cynthia Whitney,
Chief, Epidemiology Group, National Center for Infectious
Diseases (NCID)
Centers for Disease Control and Prevention (CDC)
- 11:00-11:20a.m** ***Community acquired pneumonia in adults***
Thomas Marrie, M.D.
Chair, Department of Medicine, University of Alberta
- 11:20-11:40a.m** ***Data and mathematical modeling of serotype coverage***
 - *Possible serotype replacement*
 - *Strengths & limitations of the model*
 - *Trends in pneumococcal disease as population ages*Alicia Fry, M.D., MPH
Medical Epidemiologist
NCID/CDC
- 11:40-12:00noon** ***Panel Discussion: Profile of risk factors for pneumococcal disease***
Cynthia Whitney, Thomas Marrie, Alicia Fry
- 12:00-1:00pm** **Lunch**

Polysaccharide vaccine (PS): How much protection does a PS vaccine provide against pneumococcal disease at various ages? (1:00-2:40p.m)

- 1:00-1:20p.m.** Chair: Daniel Musher, M.D.
Professor of Medicine and Microbiology/Immunology,
Head of Infectious Disease, VA Hospital
- 1:20-1:40p.m** ***Methods for assessing level and biological activity of antibody levels***
Levels and biological activity after vaccination in adults of different ages
George Carlone, M.D.
Chief, Respiratory Diseases Immunology Section
NCID/CDC

1:40-2:00p.m.

Revaccination:

- *Antibody levels*
- *Safety*

Merck Representative

2:00-2:20p.m

Protection: level and duration

- *Invasive vs. non-invasive disease*
- *Reasons for discrepancies in the literature*

David Fedson, M.D.

2:20-2:40p.m

***Polysaccharide vaccine strengths & weaknesses:
revaccination, immune correlates in adults***

Panel discussion: Daniel Musher, George Carlone, David Fedson

2:40-2:50p.m

Break

Conjugate vaccine: Could a conjugate vaccine of sufficient valency and coverage protect adults against pneumococcal disease? (2:50-4:00p.m)

2:50-3:00p.m

Chair: David S. Stephens, M.D.
Professor of Medicine
Emory University School of Medicine

3:00-3:20p.m

Conjugate vaccines:

- *Duration of immune response and breadth of immune response.*
- *Correlate of immunity in adults: what do we know?*
- *Sequential use of PS and conjugate; dose, duration, memory.*

Peter Paradiso, Ph.D.
Vice President, Scientific Affairs/Research Strategy
Wyeth Vaccines

3:20-3:40p.m

***Indirect effects- herd immunity
Prevention of pneumococcal pneumonia, radiographic endpoints***

James Watt, M.D., M.P.H.
Assistant Scientist, Center for American Indian Health,
Johns Hopkins Bloomberg School of Public Health

3:40- 4:00p.m

Panel Discussion: Conjugate vaccine research needs and path forward. Can carriage of pathogen or herd immunity be used as an endpoint? What is known about duration of immunity?

David Stephens, Peter Paradiso, James Watt

Pneumococcal protein vaccines (4 :00-5 :30pm)

4:00-4:10p.m

Review of the field of common protein vaccines

Chair: Mark Steinhoff, Ph.D.

Professor, Johns Hopkins University

4:10- 4:30p.m

Rationale : Why should we have a protein antigen?

David E. Briles, Ph.D.

Professor of Microbiology and Pediatrics, University of Alabama at Birmingham

4:30 -4:50p.m

Conjugates and proteins as part of the development of an adult pneumococcal vaccine

Jan T. Poolman, Ph.D.

Director, Bacterial Vaccine R&D
GSK Biologicals

4:50-5:10p.m

Development of the Aventis Pasteur pneumococcal protein vaccine

Elaine Wang, M.D., C.M., M.Sc.

Vice President

Clinical Development, Aventis Pasteur, Ltd

5:10-5:30p.m

Panel Discussion: Mark Steinhoff, David Briles, Jan Poolman, Elaine Wang

Pneumococcal Disease Prevention in Adults: Potential Vaccine Strategies

Day 2-September 10, 2003

Trial Designs and Endpoints: What would it take to license a new vaccine? What would it take to recommend a major new use for a licensed vaccine? (8:30 a.m–12:30 p.m)

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| 8:30-8:45 a.m | <i>Introduction to the Issues</i> Steve Black, M.D. Research Scientist Kaiser Permanente |
| 8:45 – 9:20 a.m | <i>Statistical considerations, non-inferiority, Correlates of protection</i> Brian Plikaytis, M.Sc. Chief, Biostatistics Section NCID/CDC |
| 9:20 – 9:50 a.m | <i>Clinical Issues in Trial Design for a new pneumococcal vaccine.</i> Jill Hackell, M.D. Assistant Vice President, Scientific Affairs and Research Strategy Wyeth |
| 9:50-10:10 a.m | Break |
| 10:10-10:40am | <i>Specificity versus Sensitivity: Tradeoffs in Choice of Outcomes.</i> Robert Kohberger, Ph.D. Vice President, Planning and Project Management Wyeth Research |
| 10:40-11:10a.m | <i>FDA research and viewpoint on endpoints for licensure.</i> Carl Frasch, Ph.D. Research Scientist, Laboratory of Bacterial Polysaccharides Center for Biologics Evaluation and Research FDA |
| 11:10-11:40 a.m | <i>FDA's viewpoint on design of trials for licensure of new vaccines and establishment of new indications for currently licensed vaccines.</i> |

Doug Pratt, M.D., M.P.H.
Supervisory Medical Officer, Vaccines Clinical Trials
Branch, FDA

11:40-12noon

Panel Discussion: Steve Black, Robert Kohberger, Jill
Hackell, Carl Frasch, Doug Pratt, Brian Plikaytis

12:00-12:30pm:

Summary and Overview of Issues

Benjamin Schwartz, M.D.
Deputy Director, National Immunization Program
Epidemiology and Surveillance Division
CDC